

CORNEAL REFRACTIVE SURGERY (ICD9 V802A/V802B)

Revision October 2005

This policy has been revised to reflect current changes in the management and processing of waivers and exception to policies since the acceptance of LASIK, PRK, and LASEK for initial applicants and rated aviation personnel. Uncomplicated and successful completion of LASEK or PRK to improve visual acuity with normal post-surgical assessment as outlined below will not require a waiver or exception to policy—it will be annotated as *information only*.

LASIK, still under investigational protocols, requires a waiver/exception to policy for aviation personnel.

It is not the intent of this policy to obligate any resources not readily available or to serve as swaying personnel to one type of surgery or another. All three elective surgical techniques still require the same post-operatively evaluations and tests—the only difference for the flight surgeon/APA is submission on the DD2808 for PRK and LASEK, or in the form of an abbreviated AMS for LASIK.

AEROMEDICAL CONCERNS:

Corneal refractive surgery is indicated for the correction of refractive error (myopia, hyperopia or astigmatism). Although there are presently five broad categories of corrective procedures, only three are currently acceptable aeromedically and may be considered as outlined above:

1. Surface altering procedures - photorefractive keratectomy (PRK) and laser epithelial keratomileusis (LASEK)
2. Lamellar procedures - laser-assisted in situ keratomileusis (LASIK)

Unacceptable aeromedical procedures are as follows and will not be considered for waiver at present:

1. Intracorneal procedures - intracorneal ring (ICR) implants
2. Intraocular procedures - anterior or posterior chamber intraocular lens (IOL)
3. Incisional procedures - radial keratotomy (RK)
4. Elective monocular surgical corrective procedures of any type where the outcome alters depth perception

Currently, LASIK is the most common of these procedures. PRK and LASIK have similar results in uncorrected visual acuity improvement at 6 months but differ in technique and immediate post-operative results. Noted information regarding the three aeromedically allowable procedures are as follows:

PRK - removing the corneal epithelium followed by the application of a series of fine laser ablations to re-sculpt the cornea. PRK lases through the basement membrane of the surgically removed epithelium and sculpts the corneal stroma to an average depth of 70microns (typical corneal depth 550 microns). During the first weeks after the procedure the surface epithelium must repopulate the corneal surface and during this period there is discomfort and fluctuating vision. Some studies suggest there is increased risk of haze at the treated interface with increased ultraviolet exposure due to the destruction of the basement membrane even years later.

LASEK - similar to PRK in its depth of corneal involvement, but utilizes a flap technique similar to LASIK (see below). The epithelial flap is made with a 70 micron deep pre-incision and the flap is removed mechanically after treatment with a dilute alcohol solution. After flap displacement, an excimer laser sculpts the corneal stroma. One benefit to this procedure is that post surgical flap displacement, while more likely due to the thinness of the flap, is actually less likely to cause permanent vision change as compared to the thicker (deeper) LASIK flap.

LASIK - a surgical blade is used to create a hinged flap approximately 160microns thick. This flap is laid back and the stromal bed treated with the laser. When the flap is repositioned, vision is generally excellent immediately and there is no significant discomfort. LASIK has the theoretic risk of displacement of this flap, however preliminary basic science studies and clinical studies in the Airborne and Ranger student

populations as well as the experience in the civilian population does not seem to support this concern as being of any operational or clinical relevance. The incidence of displacement of the flap is extremely low and the risk decreases with time. LASIK is currently the most popular procedure in civilian clinics due to the decreased level of pain, faster immediate results, and decreased haze per patient survey. Long term refractive correction and patient satisfaction are similar in LASIK and PRK.

ADVANTAGES: Prior to FDA approval, extensive clinical studies were performed to assess PRK safety and efficacy. Ten year follow-up data is available from some of the studies conducted. More recently, the pool of those eligible for treatment has expanded to include more severe forms of myopia, as well as hyperopia and astigmatism. Potentially 80-90% of people who require glasses for distance vision may be eligible for PRK. It is an effective procedure, with up to 95% of treated patients not needing glasses to achieve 20/40 distance vision or better. Approximately 75% of patients achieve 20/20 vision. The results may not be quite as good among patients with more extreme forms of myopia, hyperopia or astigmatism. The visual improvement appears to remain stable after healing from the surgery. Developing wavefront technology holds the promise of custom corneal ablations to produce “super-vision” (20/10 - the theoretical anatomic limit of vision - statistically occurs naturally more frequently in aviators attending the Navy’s Top Gun Program).

DISADVANTAGES: As with any surgical procedure, there may be side effects and complications. Most of these are short term and resolve within a few weeks post-op. Some may take longer to resolve or, in a small percentage of cases, could be permanent. These include decreased night vision, glare sensitivity, and worsening of the pre-operation best vision due to scar formation and other effects of the healing process. With both PRK and LASIK, it is not uncommon for up to 10% of patients to require retreatment with the laser to “fine tune” the desired corrective effects of the procedure.

While the final visual acuity results are identical for PRK and LASIK, there is a longer recovery time following PRK. Finally, though it is not anticipated that adverse complications will occur 10 or more years after the surgery, there is no data available to determine what, if any, changes may develop later in life.

RESPONSIBILITIES:

Flight Surgeons/APAs: For initial applicants and newly surgically corrected aviation personnel, Flight Surgeons/APAs complete the FDME/FDHS, noting the presence of Corneal Refractory Surgery (Block 67, DD 2808), and complete the additional work-up elements below for inclusion with the FDME/FDHS in Block 73, DD2808, or once added to AERO on the page 4. PRK and LASEK patients meeting all of the below standards may be submitted as “Qualified.” PRK and LASEK patients not meeting all of the below standards along with LASIK patients will be noted as “DQ, AMS to follow” and requires submission of an abbreviated AMS for waiver or exception to policy consideration. Flight Surgeons will ensure aviation personnel with Corneal Refractive Surgery meet all annual information requirements IAW current APL.

US Army Aeromedical Research Laboratory (USAARL): USAARL will assist USAAMA in review of exception to policy or waiver requests submitted for LASIK patients for future or current aviation personnel and will provide recommendations to USAAMA. USAARL will administer the visual performance battery to applicable categories of personnel, as described below. USAARL will provide USAAMA with the data obtained for entry into the AEDR.

UPDATED STANDARDS:

PRK and LASEK are no longer disqualifying for aviation duty if the proper post-procedural requirements are met. LASIK is disqualifying, but acceptable for waiver or exception to policy if the proper post-procedural requirements and standards are met. Intracorneal and intraocular procedures are not waiverable for the Army or Army aviation

Initial Applicants (Class 1A/1W/2F/3/ 4) : Applicants undergoing PRK or LASEK may be considered qualified and noted as *Information Only* provided meeting standards. Applicants failing to meet post-

operative standards with PRK or LASEK will require an AMS for exception to policy on a case by case basis. Applicants undergoing LASIK will continue to be considered for an exception to policy only as part of the USAARL research modified protocol with an accompanying AMS on a case-by-case basis.

Rated Aviation Personnel (Class 2/2F/3/4): Personnel undergoing refractive surgery must receive authorization from their commanding officer prior to the procedure. Commanders should be advised that the procedures have a 6-12 week recovery period before aviation duties can be resumed (Appendix 1).

Personnel undergoing PRK or LASEK will qualified *Information Only* provided meeting standards. Personnel failing to meet post-operative standards with PRK or LASEK will be considered *Disqualified* and require an AMS for waiver on a case by case basis. Personnel undergoing LASIK will continue to be considered for a waiver as part of the USAARL research modified protocol with an accompanying AMS on a case-by-case basis.

INFORMATION REQUIRED for ALL TYPES OF CORNEAL REFRACTIVE SURGERIES:

- ☐ Detailed pre-operative, operative, and post-operative refractive surgery records (Appendix 2). Post-operative information from ophthalmologist or optometrist should be annotated on DD2808 (Block 73 until page 4 in AERO is established) and must include the following:

1. Manifest refraction (at least 2 refractions one month apart to establish stability)—post-surgically, must meet standards for refraction for aviation class.
2. Visual acuity (best corrected 20/20 each eye)—post-surgically, must meet standards for visual acuity. Personnel worse than 20/20 and correctable to 20/20 will be required to wear corrective lenses while performing aviation-related duties.
3. Slit lamp examination documenting no residual haze or other complications.
4. Corneal topography (post-operative topography map)—Color topography must be mailed in for review for LASIK applicants. PRK and LASEK patients require comment of “acceptable” from ophthalmologist or optometrist.
5. Contrast Sensitivity (5% contrast using the Precision Vision backlit chart)—must pass 20/60 or better. Personnel worse than 20/60 require AMS for consideration of waiver. The preferred test is the 5% contrast test; however, the following tests may be submitted in lieu of the 5% contrast test:
 1. BVAT low contrast acuity (set on 5%)
 2. Bailey-Lovie 10% low contrast acuity test
 3. Pelli-Robson Contrast Sensitivity Test
 4. Small Letter Contrast Test
 5. VisTech or FACT Contrast Sensitivity Test

- ☐ Document that at least 3 months (for initial applicants) or 6 weeks (for current aviation personnel) have elapsed since surgery or re-treatment and evidence of stable refractive error is demonstrated by two separate examinations performed at least one month apart.

FOLLOW-UP:

The five year comprehensive flying duty medical examination (FDME) must include an optometry/ophthalmology consult with completion of a slit lamp examination of the cornea, manifest refraction, corrected visual acuity and 5% contrast sensitivity test. The 5% contrast test is not required for follow-up for classes 2F, 3, and 4 but shall be completed if available. A contrast sensitivity test is required for class 2 personnel.

TREATMENT: Per appropriate surgical protocols.

DISCUSSION:

Since allowing PRK, LASEK, and LASIK, the trend in AAMA has been that those personnel with good surgical outcomes, passing all 5 of the above post-operatively tests and standards have gone on to receive a

waiver or exception to policy without subsequent aeromedical problems. Those with a less than favorable outcome have not progressed as easily to receiving a waiver or exception to policy. Corneal refractive surgery will optimally result in less optometric support before and during deployment to Stability and Support Operations as well as combat operations. There is a significant medical logistics “footprint” of combat health support activities providing corrective lenses and protective mask inserts that may be lessened. This is especially important in current rapid deployment, high ops tempo environments. Corneal refractive surgery is an additional benefit in the continuous development of new man-machine interfaced weapons based on routinely updated detailed vision parameters. This is especially important for increasingly complex flight environments where corrective lenses would be a hindrance.

Appendix 3 includes a vast amount of information on corneal refractive surgery and the progress of the research protocol to date. Pertinent to this APL is the vast information pertaining to LASIK candidates and should be reviewed with candidates. Advantages and disadvantages of corneal refractive surgery procedures have been identified and will be further elucidated by the continuing research. In order to do this, there are two study arms in the USAARL programs: one for accessions into aviation (which closed to new applicants 1 OCT 04) and one for active aviation personnel who desire the procedure. The accession arm will follow subjects who have had LASIK and who meet criteria specified in the USAARL protocol. The other arm will include trained aviation personnel upon whom LASIK has been performed at the US Army Aeromedical Center or a DOD medical treatment facility (IAW [AR 40-3](#), Chapter 2-11). USAARL is responsible for providing study results and any required documentation to the Department of Defense Accessions Medical Standards Analysis and Research Activity (ASMARA) at the US Army Center for Health Promotion and Preventive Medicine (CHPPM).

APPENDIX 1. Aviation Commander’s Authorization

APPENDIX 2. Medical Release and Checklist for Eye Care Provider

APPENDIX 3. Flight School Applicant Fact Sheet (posted also on USAARL Website)

Appendix 1: Aviation Commander's Authorization

Memorandum to: Unit Flight Surgeon

CC: Ophthalmology, Refractive Surgeon

Subject: Authorization for Aircrew members to receive refractive surgery under the Aeromedical Policy Letter for Refractive Surgery and the Corneal Refractive Surgery Surveillance Program.

1. _____, SSN _____ is authorized to receive refractive surgery per the guidance outlined in the Aeromedical Policy Letter: Corneal Refractive Surgery.

2. This authorization is based on the following understandings:

a. This authorization does not constitute a medical waiver; it only authorizes the individual to have refractive surgery. The individual will be DNIF for at least 6 weeks, up to a maximum 12 weeks. The medical waiver request will be submitted to USAAMA upon receipt of information from the flight surgeon as to the successful outcome of the individual's surgical procedure. USAAMA will determine if the individual meets the medical waiver requirements when the applicant's eyes and vision meet and retain FDME standards and all requirements for waiver have been met.

b. In approximately 2-3 of every 1,000 refractive surgery procedures (0.2 to 0.3%), the individual will not recover 20/20 best-corrected vision after surgery. Individuals who fall in this category will be evaluated by USAAMA to determine whether a waiver to continue on flight status may be issued. Although slight, there is a possibility the individual may lose his/her flight status in the event of significant visual loss that cannot be resolved.

c. Questions about the program may be directed to USAARL at 334-255-6810; questions about waivers to USAAMA at 334-255-7430; questions about refractive surgery to the local eye care provider.

d. A copy of this correspondence will be kept on file in the local flight surgeon's office.

3. POC is the undersigned at _____.

Commander's Signature Block

Appendix 2: Request for Release of Medical Records

(completed by waiver applicant and provided to eye care provider for completion)

From: (enter your information)

Date:

To: (enter eye clinic information)

Subject: Request for records related to refractive surgery procedure

1. Request a copy of records pertaining to my refractive surgery be provided to: (enter unit flight surgeon information and address)
2. The following information is needed (see attached Checklist for Eye Care Provider):

Date of procedure

Type of procedure (PRK, LASEK, or LASIK)

Type of laser (brand name)

Ablation parameters (size of ablation zone, microns of tissue removed, number of pulses, if available)

Amount of correction (sphere, cylinder and axis)

Pre-operative refraction and date (specify manifest or cycloplegic)

Follow-up refractions with visual acuities and dates (most current refraction and as many postoperative refractions as possible)

Slit lamp assessment of cornea (presence or absence of haze or other complications)

Latest **post-operative COLOR** corneal topography (instantaneous or tangential corneal maps)

Contrast Sensitivity (preferred test is the 5% low contrast letter acuity)

Typed or Printed Name

Signature

Demographics Required (Applicant to complete):

Last Name: _____ First Name: _____ M.I. _____

Mailing Address: _____

E-mail Address: _____

Home/Cellular Phone: _____

Date of Birth: _____ SSN: _____

Checklist for Eye Care Provider (Surgeon/Doctor to complete below):

Surgeon/Doctor's Name: _____

Clinic Address: _____

Clinic Phone: _____ Clinic Name: _____

Date of Procedure: _____ Type: (circle one) PRK or LASIK

Laser Used: (Manufacturer) _____ (Model#) _____

Ablation Parameters (Complete below, and if available, attach copies of laser printouts)

OD: Size of ablation: _____ mm Tissue removed: _____ microns # of pulses: _____

OS: Size of ablation: _____ mm Tissue removed: _____ microns # of pulses: _____

Amount of correction programmed into laser

OD: _____ OS: _____

Pre-operative Refraction

OD: _____ OS: _____

Did the applicant require any enhancement procedures? Yes _____ No _____

(If yes, provide details as above & below)

Follow-up Examinations (include most recent and 2 prior examinations—3 total)

<u>Date:</u> _____	<u>Refraction:</u> _____	<u>Visual Acuity</u>	<u>Corneal Haze*</u> (circle one)
	OD _____ OS _____	OD _____ OS _____	OD 0 1 2 3 4 OS 0 1 2 3 4
	OD _____ OS _____	OD _____ OS _____	OD 0 1 2 3 4 OS 0 1 2 3 4
	OD _____ OS _____	OD _____ OS _____	OD 0 1 2 3 4 OS 0 1 2 3 4

***Haze 0-4 scale:** 0=No Haze, 1=Trace, 2=Minimal, 3=Moderate, 4=Iris details obscured.

Corneal Topography (include a color copy of most recent post-operative corneal topography using the TANGENTIAL or INSTANTANEOUS map display option)

Topographer Manufacturer: _____

Topographer Model: _____

Date of topographies: _____

Contrast Sensitivity (attach copy of post-operative results, if test available)

Test Manufacturer/Model: _____

Date of contrast test: _____

Test Conditions:

Room Lights On? (circle one) Yes No

Backlit Chart? (circle one) Yes No

Distance to Test? _____ m

% Contrast? (if letters) _____ %

Results:

OD: _____

OS: _____

Does applicant report any subjective visual changes? (i.e. increased glare, starbursts, halos, etc.)

***For Class 1A/1W** (MUST complete a post-operative cycloplegic refraction, noting normal refractive DVA/NVA with best correction, and IOP's if your 1A/1W FDME data was pre-operative.)

Distant Vision

Near Vision

OD 20/____ Corrected to 20/____

20/____ Corrected to 20/____

OS 20/____ Corrected to 20/____

20/____ Corrected to 20/____

Cycloplegic Refraction

OD: _____ OS: _____

Intraocular Tension

OD: _____ OS: _____

Thank you for completing the information. Please return this form and supporting documents to your flight surgeon.